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Biden Announces \$1 Million for Delaware in Historic Healthcare Fraud Settlement

GlaxoSmithKline will pay \$3 billion nationally and plead guilty to criminal activity

Wilmington – Attorney General Beau Biden announced today that the state of Delaware is set to receive nearly \$1 million in a proposed national settlement between approximately 25 states, the federal government, and drug manufacturer GlaxoSmithKline (GSK). The \$3 billion settlement, which is the largest of its kind in U.S. history, resolves claims that GSK operated various illegal schemes in pricing and marketing its drugs. GSK has also agreed to plead guilty to federal criminal charges connected to improper drug labeling and reporting to the Food and Drug Administration (FDA).

“Prescription medications can literally save lives, and they improve the quality of life for millions. At the same time, though, drug manufacturers have an obligation to follow regulations put in place to keep consumers safe and healthy,” said Biden.

Allegations against GSK claim that the company carried out an illegal plan to market and sell certain drugs by promoting them for non-FDA-approved uses, falsely representing the drugs’ safety and efficacy, offering kickbacks to medical professionals, and underpaying rebates owed to Medicaid and other federally-funded healthcare programs for purchasing GSK-manufactured drugs.

Of the total settlement recovery, \$2 billion in damages and civil penalties will go toward compensating federal healthcare programs, including Medicaid, for harm suffered as a result of GSK’s alleged illegal practices. Delaware-based claims have led to over \$2 million in recoveries, nearly half of which will go to the state directly through the Division of Medicaid and Medical Assistance within Delaware Health and Social Services.

Specifically, the settling states and federal government accuse GSK of:

- Marketing the depression drug Paxil for off-label uses, such as use by children and adolescents.
- Marketing the depression drug Wellbutrin for off-label uses, such as for weight loss and treatment of sexual dysfunction, and at higher-than-approved dosages.
- Marketing the asthma drug Advair for off-label uses, including first-line use for asthma.
- Marketing the seizure medication Lamictal for off-label uses, including bipolar depression, neuropathic pain, and various other psychiatric conditions.

- Marketing the nausea drug Zofran for off-label uses, including pregnancy-related nausea.
- Making false representations regarding the safety and efficacy of Paxil, Wellbutrin, Advair, Lamictal, Zofran, and the diabetes drug Avandia.
- Offering kickbacks, including entertainment, cash, travel, and meals, to healthcare professionals to induce them to promote and prescribe Paxil, Wellbutrin, Advair, Lamictal, Zofran, the migraine drug Imitrex, the irritable bowel syndrome drug Lotronex, the asthma drug Flovent, and the shingles and herpes drug Valtrex.
- Submitting incorrect pricing data for various drugs, thereby underpaying rebates owed to Medicaid and other federal healthcare programs.

Also part of the settlement, GSK has agreed to pay a \$1 billion criminal fine and plead guilty to misdemeanor charges of violating the federal Food, Drug, and Cosmetic Act by introducing Wellbutrin and Paxil into interstate commerce with labeling not in accordance those drugs' FDA approvals. GSK will also plead guilty to failing to report certain clinical data regarding Avandia to the FDA.

The settlement is based on four *qui tam*, or whistleblower, actions initially brought by private individuals, as well as investigations conducted by the U.S. Attorney's Office for the District of Massachusetts and the Civil Frauds Division of the U.S. Department of Justice.

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